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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,747	01/10/2005	Masahiko Koike	084437-0174	3250

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EXAMINER	
PALENIK, JEFFREY T	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,747	KOIKE ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8,10,13 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-8,10,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

STATUS OF THE APPLICATION

Receipt is acknowledged of Applicants' Request for Continued Examination (RCE), as well as their Amendments and Remarks all of which was timely filed on 9 June 2009. Receipt is also acknowledged of Applicants' response to the Notice of Non-Compliance, filed 28 August 2009. Said filings are entered on the record. The Examiner further acknowledges the following:

No additional claims have been canceled.

Claims 1 and 10 have been amended to clarify that the coating dispersion which comprises an organic solvent also comprises polyvinylpyrrolidone. The amendment is supported by Applicants' originally filed disclosure (e.g. see pg. 2-3, paragraphs "1" and "9").

Claim 4 apparently has been corrected to reflect Applicants' amended claim 4, per the claim set filed 20 August 2008. This amendment is considered by the Examiner as being proper since the claims which were previously rejected as "Final" properly captured the amendment.

The addition of claims 13 and 14 is supported by the original disclosure, for example, on page 3 (see paragraph "11" and "12").

No new matter has been added.

As such, claims 1, 4-8, 10, 13 and 14 now represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

No Information Disclosure Statements (IDS) have been filed for consideration.

WITHDRAWN REJECTIONS

Rejection under 35 USC 103(a)

Applicants' remarks concerning claims 1, 4-8 and 10 which were previously maintained as "finally" rejected under 35 USC 103(a), as being unpatentable over the combined teachings of Timmins et al. (USPN 6,031,004) and Cutie et al. (WO 91/82875), have been considered in light of the amendments made to base claims 1 and 10, and are **persuasive**. Namely, Applicants' remarks concerning the lack of a specific teaching of pioglitazone HCl being coated to the surface of a metformin HCl core are sufficient enough to overcome the rejection of record. Since the combined teachings of the references are no longer considered as reading on the base limitations, said rejection now stands **withdrawn**.

DECLARATION UNDER 37 CFR §1.132

The Declaration under 37 CFR 1.132 filed 9 June 2009, is acknowledged and has been reviewed, but is insufficient as evidence in overcoming the rejection of the instant claims based upon the combined teachings of Timmins and Cutie as set forth in the last Office Action. It appears that Applicants compare the preparation of Example 1 of the instant disclosure to a second formulation (e.g. Comparative Example 1) which is prepared in the same manner as Example 1 except that it uses water rather than ethanol. The two formulations are then compared on the basis of their ability to release pioglitazone HCl. Though the results demonstrate that the ethanol-based formulation versus the water-based formulation exhibits better dissolution in the required timeframe, it is unclear how the experiment bears any relevance to the above withdrawn rejection. As such, the Declaration, while having been fully considered, is **not persuasive**.

NEW OBJECTIONS/REJECTIONS

In light of Applicants' remarks, the withdrawn rejection discussed above, as well as the addition of new claims 13-14, the following rejection has been newly added:

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-8, 10, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. (WO 01/35940 A2).

The instantly amended base claims are drawn to a method of producing a coated preparation wherein said coating comprises pioglitazone hydrochloride which is dispersed within an organic solvent, which further comprises polyvinylpyrrolidone as a "coating base" which is soluble in said organic solvent. Dependent claims 7 and 8 further define the organic solvent of claim 1 as an alcohol and ethanol, respectively. Claims 4-6 further define the core active ingredient as metformin HCl. New claims 13 and 14 recite functional dissolution profile limitations for the compositions produced by the methods of claims 1 and 10, respectively. Regarding the recited release profile limitations; until some material differences in the properties of the composition are demonstrated, said limitations are considered by the Examiner to be directed toward composition which is produced by the instantly claimed method.

Lewis expressly teaches a process for preparing a pharmaceutical composition comprising a thiazolidinedione, metformin HCl and a pharmaceutically acceptable carrier wherein said thiazolidinedione is formulated onto the surface of the metformin HCl (claim 13). The process is defined in more detail whereby the metformin hydrochloride is preferably compacted to form the core of the dosage after which the thiazolidinedione is formulated and coated onto said core (pg. 4, line 34-35). Embodiments for the thiazolidinedione component are taught (pg. 3, lines 12-23), where pioglitazone hydrochloride is a preferred compound (pg. 3, line 23). Preparation of the thiazolidinedione-based coating composition is taught (pg. 5, lines 1-16). Thiazolidinedione is taught as being dispersed in a liquid prior to its application to the surface of the metformin core, wherein said liquid is taught as being an organic solvent such as ethanol (pg.

5, lines 1-3). Additional optional (e.g. as necessary) excipient ingredients which may be used in the formulation include components such as binders or disintegrants, both of which are defined by Lewis as including polyvinylpyrrolidone (pg. 5, lines 11-15 and 31-34).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the invention to devise a method whereby a PVP/ethanol/pioglitazone-based dispersion is prepared and coated onto a metformin HCl core. It is noted that though PVP is taught as being used as a disintegrant, it is not expressly taught as being incorporated into the dispersion coating of the dosage. However, the ordinarily skilled artisan would have been highly motivated to admix PVP into the ethanol-based dispersion coating because of its ability to act as a disintegrating agent. The reference teaches that an excipient such as PVP is incorporated as necessary into the dosage. Such a teaching would minimally suggest to the ordinarily skilled artisan that achieving an immediate- or quickened-release of pioglitazone HCl from the dosage, could be accomplished by incorporating a disintegrating agent.

Thus, based on the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

All claims have been rejected; no claims are allowed.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615